

Application No. 08/819,669

Amendment dated November 19, 2007

Reply to Office Action of October 23, 2007

Docket No.: NY-LUD 5253-US5-DIV

Pertinent case law on 35 U.S.C. § 102(f) in the context of ex parte prosecution is limited; however, it is clear. In Ex parte Kusko, 215 USPQ 972 (PTO Bd. App. 1982), the Board held:

“Where an applicant by oath or declaration states that he is the sole inventor of a particular invention, strong evidence is required to reach a contrary conclusion.”

Kusko at 974. The Board went on to hold that while 35 U.S.C. § 102(f) does not include references to dates of invention or relative timing:

“Nevertheless it is clear that most, if not all, determinations under § 102(f) involve the question of whether one party derived an invention from another, and the relative dates of the events in question are important and are considered in deciding such issues.”

With this framework in mind, it is submitted that the evidence does not establish that the currently named applicants did not invent the claimed invention. Rather, it establishes that they did.

U.S. Patent No. 5,843,448, is ultimately a continuation in part of the subject application. See the priority claim, which ultimately refers back to PCT/US92/04354 which is the parent of the current case. In other words, the disclosure of the ‘448 patent by definition differs from what is disclosed in the current application. A cursory review of the specification will confirm this.

Indeed, the ‘448 patent does NOT profess to teach MAGE-1 *per se*. Please note column 5, lines 26-30:

“The cell line MZZ-MEL3.1 described in, e.g., Van den Eynde, et al., Int. J. Cancer, 44:634-640(1989) and in the parent application, cited supra, previously observed to express MAGE-1...”

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The '448 patent thus clearly contains an admission that MAGE-1 *per se* was known prior to the filing of the application leading to the '448 patent.

Also note the discussion within '448, at column 3, lines 28-35 describing Serial No. 08/807,443, which actually issued as U.S. Patent No. 5,342,774, NOT 5,842,774 as presented. A copy of U.S. Patent No. 5,342,774 is attached hereto for convenience.

If one observes the inventorship of 5,342,774, it will be seen to be identical to that of the present application. It was filed on December 12, 1991, as compared to the filing date of February 1, 1994, the parent of the '448 patent. It will also be seen that there is only one inventor in common between '448 (following correction), and '774.

What will also be seen, most significantly is that SEQ ID NO: 8 of the present case is shared with '774, i.e., the same inventors, disclosed the same nucleic acid molecule, and the same amino acid sequence.

Examples 1-34 are the same in the '774 patent, and the present application. These examples include disclosure relevant to MAGE-1.

Compare this to the '448 patent, where no empirical data are shared with '774 and as noted, supra, the '448 patent expressly refers to MAGE-1 as prior art.

It is also noteworthy that, in examining the application leading to the '448 patent, the PTO cited as art the patent which issued from 08/807,043. While the patent number is given as 5,342,024, it is submitted that this is another USPTO printing error, as this refers to an 8/94 patent of Boon, et al., (5,342,774 issued on August 30, 1994). U.S. Patent NO. 5,342,024, is entitled an "Automatic flushing device for urinal," and issued to Kim. No other patents issued to an inventor Boon in August, 1994. Hence, the record establishes that the USPTO did not find the '774 patent to disclose the same invention as was claimed in the '448 patent. As applicants are claiming what is disclosed in '774

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(from which they claim priority), there cannot be a holding that the invention claimed herein is the same as that disclosed in '448. There has already been a determination that they are NOT the same.

MPEP 706.02(g), requires that proper inventorship be presumed "unless there is proof that another or others made the invention." Indeed, Kusko, *supra*, requires strong evidence to reach a contrary conclusion.

The Examiner has pointed to nothing within the '448 patent to rebut the presumption. Undoubtedly, the '448 patent references MAGE-1; however, this does not mean that the inventors of the '448 patent invented what is now claimed. Similar disclosure in and of itself is insufficient.

While Ex parte Nishioka, 1995 WL 1768442 (Bd. Pat. App. & Int.), does not have precedential value, its analytical framework is helpful. A copy of Nishioka is attached. Note that the Board notes that the lack of coextensive disclosure between an application and a reference was relevant in its holding. As was pointed out, *supra*, there is no coextensive empirical disclosure between the current application and the '448 patent. One queries why the '448 patent was permitted to issue without a sequence listing if the invention were MAGE-1. Is it not a requirement that sequences of novel proteins and nucleic acid molecules be presented in sequence listings?

Clearly, the '448 patent was an advance relative to the first disclosure of MAGE-1. The current application has priority claims, extending back to 1991! It is entitled to patentability.

Should the Examiner not withdraw the 102(f) rejection and allow the application, an interview with the Group Director, and the Supervisory Primary Examiner is requested.

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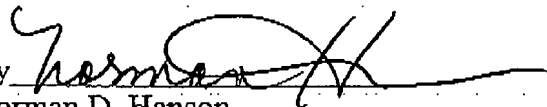
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* * *

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-0624, under Order No. NY-LUD 5253-US5-DIV (09885911) from which the undersigned is authorized to draw.

Dated: 11/19/07

Respectfully submitted,

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Attachments: Copy of U.S. Patent No. 5,342,774
Copy of Nishioka

Westlaw.

1995 WL 1768442 (Bd. Pat. App. & Interf.)

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The references relied on by the examiner are:

1995 WL 1768442 (Bd. Pat. App. & Interf.)

THIS OPINION WAS NOT WRITTEN FOR PUBLIC-
ATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)

EX PARTE KENJI NISHIOKA, JOHN S. MCMUR-
RAY, B. MONTGOMERY PETTITT AND FAHAD
AL-OBEIDINO DATE REFERENCE AVAILABLE FOR THIS
DOCUMENTKenneth D. Goodman
Arnold, White & Durkee
P.O. Box 4433
Houston, TX 77210Before WINTERS and WILLIAM F. SMITH
Administrative Patent JudgesMcKELVEY
Senior Administrative Patent Judge.
WINTERS
Administrative Patent Judge.

ON BRIEF

DECISION ON APPEALThis appeal was taken from the examiner's decision re-
jecting claims 1 through 6, which are all of the claims in
the application.

Claim 1 is representative:

1. A peptide selected from the group consisting of:
cyclo[Thr-Lys-Pro-Arg-Gly] (SEQ ID NO. 1)
and pharmaceutically acceptable salts thereof;
and
cyclo[Thr-Lys-Pro-Arg-Asp] (SEQ ID NO. 2)
and pharmaceutically acceptable salts thereof.

1995 WL 1768442 (Bd. Pat. App. & Interf.)

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Chipens et al. (Chipens II)

4,434,095

Feb. 28, 1984

Hahn

4,816,449

Mar. 28, 1989

Stabinsky, Y., et al. (Stabinsky), "THE PHAGOCYTOSIS STIMULATING PEPTIDE TUFTSIN: FURTHER LOOK INTO STRUCTURE-FUNCTION RELATIONSHIPS", *Molecular & Cellular Biochemistry*, Vol. 30, No. 3, pp. 165-170 (1980).

Chipens, G.I. (Chipens I), "ELONGATED AND CYCLIC ANALOGUES OF TUFTSIN AND RIGIN", *Peptides, Proceedings of European Peptides Symposium*, 16th, pp. 445-450 (1981).

Siemion, I.Z., et al. (Siemion), "Tuftsin analogs and their biological activity", *Molecular and Cellular Biochemistry* Vol. 41, pp. 99-111 (1981).

Nikiforovich, G.V., "Biologically active conformation of tuftsin", *International Journal of Peptide Protein Research*, Vol. 23, pp. 271-275 (1984).

O'Connor, S.D., et al. ^[FN2] (O'Connor) "Quenched Molecular Dynamics Simulations of Tuftsin and Proposed Cyclic Analogues", *Journal of Medicinal Chemistry*, Vol. 35, No. 15, pp. 2870-2881 (1992).

The appealed claims stand rejected as follows: (1) Claims 1, 2, 4 and 5 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Chipens (I) and Nikiforovich; (2) claims 1, 3, 4 and 6 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Chipens (I) and Hahn; (3) claims 1, 2, 4 and 5 under 35 U.S.C. § 103 as unpatentable over Siemion or Stabinsky, either of those "primary references" in view of Chipens (II); and (4) claims 1 through 3 under 35 U.S.C. § 102(f) because applicants themselves did not invent the subject matter sought to be patented.

On consideration of the record, we shall not sustain these rejections.

SECTION 103

*2 Having reviewed the Appeal Brief, Reply Brief, and Examiner's Answer, we conclude that the examiner's rejections under 35 U.S.C. § 103 are untenable. Each appealed claim recites the pentapeptide *cyclo[Thr-Lys-Pro-Arg-Gly]* or *cyclo[Thr-Lys-Pro-Arg-Asp]* fully cyclized in a "head-to-tail" manner, i.e., by coupling the alpha-amino group of the Thr to the carboxyl group of Gly or Asp. In

our judgment, the only reason, suggestion, or motivation to arrive at those cyclized pentapeptides stems from appellants' specification and not from the cited prior art. It follows, in our judgment, that the rejections under 35 U.S.C. § 103 are based on the impermissible use of hindsight and cannot stand. The rejections under 35 U.S.C. § 103 are reversed.

SECTION 102(f)

Claims 1 through 3 stand rejected because, according to the examiner, applicants themselves did not invent the subject matter sought to be patented. 35 U.S.C. § 102(f). In setting forth this rejection, the examiner (1) cites the O'Connor publication entitled "Quenched Molecular Dynamics Simulations of Tuftsin and Proposed Cyclic Analogues"; and (2) refers to O'Connor's description of ctuf2 (*cyclo[Thr-Lys-Pro-Arg-Gly]*) at page 2878 second column and ctuf4 (*cyclo[Thr-Lys-Pro-Arg-Asp]*) at page 2879 second column. According to the examiner, the peptides recited in claims 1 through 3 are identically described in the O'Connor publication which is co-authored by two of the present inventors (Fahad Al-Obcidi and Montgomery Pettitt) and two others. The examiner argues that this set of facts "raises a question of inventorship" and that, in the absence of a satisfactory showing, it is unclear whether "the inventorship of the application has been properly designated". See the Examiner's Answer, page 4. We disagree.

On this record, the examiner has not established that another inventive entity conceived the invention of claims 1 through 3 and communicated that invention to applicants before July 22, 1992, the filing date of the instant application. Nor has the examiner established that the original oath accompanying this application is incorrect.

In the office action mailed June 1, 1993 (paper no. 8), page 3, the examiner invites attention to *In re Katz*, 687 F.2d 450, 215 USPO 14 (CCPA 1982). The question arises whether we have an ambiguity respecting inventorship created by the O'Connor publication, similar to the ambiguity found to exist in *Katz*, and, if so, whether this ambiguity shifts the burden of persuasion to applic-

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ants to provide a satisfactory showing which would lead to a reasonable conclusion that applicants are the joint inventors of the peptides recited in claims 1 through 3. See *In re Katz*, 687 F.2d at 455, 215 USPO at 18, where the court required a showing above and beyond the original oath accompanying the Katz patent application. We answer these questions in the negative.

*3 In *Katz*, the Chiorazzi et al. article was published before applicant's effective filing date and the examiner's rejection was predicated on 35 U.S.C. § 102(a). Here, the O'Connor article was published after applicants' filing date and the rejection is predicated on 35 U.S.C. § 102(f). We shall not pass on the question whether the analysis set forth in *Katz* in the context of a rejection under 35 U.S.C. § 102(a) applies to a fact situation arising under 35 U.S.C. § 102(f). Assuming arguendo, without deciding, that the *Katz* analysis is here applicable, nevertheless, this case is distinguishable on its facts.

As correctly pointed out by applicants (Appeal Brief, page 4), O'Connor does not disclose how to prepare the peptides ctuf2 or ctuf4. Nor does O'Connor disclose any experimental data respecting the biological activity of those peptides. Compare the instant specification, pages 4 through 12, describing the preparation of *cyclo[Thr-Lys-Pro-Arg-Gly]* and *cyclo[Thr-Lys-Pro-Arg-Asp]* and further describing the details of a Phagocytosis Assay, a Thymidine Incorporation Assay, and a Tumor cell Cytotoxicity Assay and the results of those assays using tuftsin and *cyclo[Thr-Lys-Pro-Arg-Gly]*. It can be seen that the content of the O'Connor publication with respect to the details of preparing and testing these two peptides is not coextensive with the content of the instant application.

On these facts, which differ from those in *Katz*, [FN3] we hold that co-authorship of the O'Connor publication by two of the present inventors, (Fahad Al-Obeidi and Montgomery Pettitt) and two others is not inconsistent with the named inventors in the instant application. Co-authorship does not raise a presumption of inventorship with respect to the peptides ctuf2 and ctuf4 disclosed in the publication. Nor does co-authorship here create an ambiguity which would shift the burden of persuasion to applicants to reaver inventorship in the face of a re-

jection under 35 U.S.C. § 102(f).

The rejection of claims 1 through 3 under 35 U.S.C. § 102(f) is reversed.

CONCLUSION

In conclusion, for the reasons set forth in the body of this opinion, the examiner's decision rejecting claims 1 through 6 is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

SHERMAN D. WINTERS

Administrative Patent Judge

WILLIAM F. SMITH

Administrative Patent Judge

FRED E. McKELVEY

Senior Administrative Patent Judge

FN1. Application for patent filed July 22, 1992.

FN2. O'Connor does not constitute a "prior art" reference because it was published two days after the filing date of application no. 07/918,588, the application on appeal.

FN3. In *Katz*, 687 F.2d at 453, 215 USPO at 16, the court quoted from the Board opinion under review and did not disturb the Board's finding that "[t]he Chiorazzi et al. article, as pointed out by the examiner and as acknowledged by appellant, fully describes the presently claimed therapeutic immunosuppressive agent and the method of preparing same."

1995 WL 1768442 (Bd. Pat. App. & Interf.)

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